Jazz Pharmaceuticals plc
Form 8-K
May 21, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE

SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): May 18, 2012

JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

Ireland	**001-33500**	**98-1032470**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

45 Fitzwilliam Square

Dublin 2, Ireland

(Address of principal executive offices, including zip code)

011-353-1-634-4183

(Registrant s telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

¨ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On May 18, 2012, Jazz Pharmaceuticals, Inc., a wholly owned subsidiary of Jazz Pharmaceuticals plc (the Company), submitted a Citizen Petition to the U.S. Food & Drug Administration (the FDA) addressing the legal and scientific bases for requiring *in vivo* bioequivalence studies for generic formulations of Xyrem (sodium oxybate) oral solution (Xyrem) and requesting that the FDA: publish in the FDA s publication Approved Drug Products with Therapeutic Equivalence Evaluations (known as the Orange Book) bioequivalence requirements specifying whether *in vitro* or *in vivo* bioequivalence studies, or both, are required for abbreviated new drug applications (ANDAs) referencing Xyrem; not accept for review, review, or approve any ANDA referencing Xyrem unless and until the FDA has published bioequivalence requirements in the Orange Book specifying whether *in vitro* bioequivalence studies, *in vivo* bioequivalence studies, or both, are required for such ANDAs; and require *in vivo* bioequivalence studies for any sodium oxybate drug product for which approval is sought in an ANDA referencing Xyrem to the extent such drug product differs from Xyrem in manufacturing process, pH, excipients, impurities, degradants or contaminants. The Company cannot predict when or if the FDA will respond to, or otherwise take any action with respect to, the Citizen Petition. A copy of the Citizen Petition is available in the Investors & Media section of the Company s website at www.jazzpharma.com.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY

By: /s/ Suzanne Sawochka Hooper
Name: Suzanne Sawochka Hooper
Title: Executive Vice President and General Counsel

Date: May 18, 2012